UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED, *Defendants*.	Civil Action No. 1:15-CV-145

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Mylan Pharmaceuticals Inc.; Mylan Inc.; and Mylan Laboratories Limited hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' TRADJENTA® (linagliptin) and JENTADUETO® (linagliptin and metformin hydrochloride) tablets prior to the expiration of United States Patent Nos. 8,673,927, 8,846,695, and 8,853,156.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff, Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

5. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

6. BIPI, BII, BIPKG and BIC are collectively referred to hereinafter as "Boehringer."

7. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. On information and belief, Mylan Pharms is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of West Virginia.

9. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

10. On information and belief, Defendant Mylan Laboratories Limited ("Mylan Labs") is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

11. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Labs, which, in turn is a wholly-owned subsidiary of Mylan Inc.

12. On information and belief, the acts of Mylan Pharms complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

13. Mylan Pharms, Mylan Labs, and Mylan Inc. are collectively referred to herein as "Mylan."

14. A complaint against Mylan, among other defendants, containing the same allegations as set forth herein was filed in the United States District Court for the District of New Jersey on August 4, 2015. Boehringer timely files the instant complaint in order to preserve its rights under 21 U.S.C. § 355(c)(3)(C) in the event that Mylan challenges the personal jurisdiction of the United States District Court for the District of New Jersey.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

16. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

PERSONAL JURISDICTION OVER MYLAN PHARMS.

17. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

18. On information and belief, Mylan Pharms develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

19. This Court has personal jurisdiction over Mylan Pharms because, *inter alia*, Mylan Pharms, on information and belief: (1) has substantial, continuous, and systematic contacts with this judicial district; (2) is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this judicial district; (4) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (5) maintains a broad distributorship network within this judicial district; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this judicial district.

20. Additionally, on information and belief, Mylan Pharms has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims and by filing suit in the Northern District of West Virginia.

PERSONAL JURISDICTION OVER MYLAN INC.

21. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

22. On information and belief, Mylan Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

23. This Court has personal jurisdiction over Mylan Inc. because, *inter alia*, Mylan Inc., on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (2) controls Defendant Mylan Pharms, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this State through Mylan Pharm, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

24. Additionally, on information and belief, Mylan Inc. has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims.

PERSONAL JURISDICTION OVER MYLAN LABS

25. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

26. On information and belief, Mylan Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

27. This Court has personal jurisdiction over Mylan Labs because, *inter alia*, Mylan Labs, on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (2) controls Defendant Mylan Pharm., which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district;

(3) makes its generic drug products available in this State through Mylan Pharm, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

28. Additionally, on information and belief, Mylan Labs has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims.

BACKGROUND

U.S. Patent No. 8,673,927

29. On March 18, 2014, the PTO duly and legally issued United States Patent No. 8,673,927 ("the '927 patent") entitled "Uses of DPP-IV Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '927 patent is attached as Exhibit 1.

U.S. Patent No. 8,846,695

30. On September 30, 2014, the PTO duly and legally issued United States Patent No. 8,846,695 ("the '695 patent") entitled "Treatment For Diabetes In Patients With Inadequate Glycemic Control Despite Metformin Therapy Comprising A DPP-IV Inhibitor" to inventor Klaus Dugi. A true and correct copy of the '695 patent is attached as Exhibit 2.

U.S. Patent No. 8,853,156

31. On October 7, 2014, the PTO duly and legally issued United States Patent No. 8,853,156 ("the '156 patent") entitled "Treatment For Diabetes In Patients Inappropriate For

Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Jurgen Woerle. A true and correct copy of the '156 patent is attached at Exhibit 3.

TRADJENTA® AND JENTADUETO®

32. BIPI is the holder of New Drug Application ("NDA") No. 201280 ("the NDA") for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

33. BIPI is the holder of NDA No. 201281 for linagliptin and metformin hydrochloride tablets, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages, which are sold under the trade name JENTADUETO®.

34. TRADJENTA® and JENTADUETO® are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until May 2, 2016.

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '927, '695, and '156 patents are listed in the "Orange Book" with respect to TRADJENTA®.

36. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '927, and '695 patents are listed in the Orange Book with respect to JENTADUETO® in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages.

37. The '927, '695, and '156 patents cover the TRADJENTA® product.

38. The '927, and '695 patents cover the JENTADUETO® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE '927 PATENT

39. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

40. On information and belief, Mylan submitted ANDA Nos. 208431 and 208430 (the "Mylan ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market linagliptin, for oral use, in 5 mg dosage (the "Mylan Linagliptin Product") and linagliptin and metformin, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages ("the Mylan Combination Products"), respectively. The Mylan Linagliptin Product and the Mylan Combination Products are herein collectively referred to as the "Mylan ANDA Products."

41. Mylan ANDA No. 208431 refers to and relies upon the TRADJENTA® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the Mylan Linagliptin Product and TRADJENTA®.

42. Mylan ANDA No. 208430 refers to and relies upon the JENTADUETO® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the Mylan Combination Products and JENTADUETO®.

43. Plaintiffs received letters from Mylan on or about July 13, 2015 and July 15, 2015, stating that Mylan had included certifications in the DRL ANDAs, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '695, and '156 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Mylan ANDA Products (the "Mylan Paragraph IV Certifications").

44. Mylan has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan

seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the '927 patent.

45. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

46. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

47. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '927 patent either literally or under the doctrine of equivalents.

48. On information and belief, the use of Mylan's ANDA Products constitutes a material part of at least one of the claims of the '927 patent; Mylan knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

49. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Mylan had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

51. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

52. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '927 patent.

53. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II - INFRINGEMENT OF THE '695 PATENT

54. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

55. Mylan has infringed at least one claim of the '695 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the '695 patent.

56. Mylan declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

57. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '695 patent would further infringe at least one claim of the '695 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

58. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '695 patent either literally or under the doctrine of equivalents.

59. On information and belief, the use of Mylan's ANDA Products constitutes a material part of at least one of the claims of the '695 patent; Mylan knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

60. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would contributorily infringe at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

61. On information and belief, Mylan had knowledge of the '695 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

62. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would actively induce infringement of at least one of the claims of the '695 patent, either literally or under the doctrine of equivalents.

63. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '695 patent.

64. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT III - INFRINGEMENT OF THE '156 PATENT

65. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

66. Mylan has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted Mylan ANDA No. 208431, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan Linagliptin Product prior to the expiration of the '156 patent.

67. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan Linagliptin Product in the event that the FDA approves Mylan ANDA No. 208431. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

68. Mylan's manufacture, use, offer to sell, or sale of the Mylan Linagliptin Product in the United States or importation of the Mylan Linagliptin Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

69. On information and belief, the Mylan Linagliptin Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '156 patent either literally or under the doctrine of equivalents.

70. On information and belief, the use of Mylan's Linagliptin Product constitutes a material part of at least one of the claims of the '156 patent; Mylan knows that its Linagliptin Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its Linagliptin Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

71. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

72. On information and belief, Mylan had knowledge of the '156 patent and, by its promotional activities and package inserts for its Linagliptin Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

73. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin Product would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

74. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '156 patent.

75. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A Judgment be entered that Mylan has infringed at least one claim of the '927, '695, and '156 patents by submitting the Mylan ANDAs;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '927, '695, and '156 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '927, '695, and '156 patents or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '927, '695, '156 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Defendants commercially use, offer to sell, or sell their respective proposed generic versions of TRADJENTA® and/or JENTADUETO® or any other product that infringes or induces or contributes to the infringement of the '927, '695, and/or '156 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

DATED: August 25, 2015

Respectfully submitted,

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